a control unit controlling said injection system; said control unit being so configured as to receive and analyze inspiratory gas flow data from the ventilator; and

a valve assembly in connection with the conduit to selectively allow delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said control unit to be controlled thereby;

wherein a) said control unit is so configured as to control said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow supplied to the patient so as to achieve a predetermined concentration of the gaseous substance with respect to the inspiratory gas, and b) said control unit is so configured as to vary said predetermined concentration within a plurality of inspiratory phases of the patient on the basis of said inspiratory gas flow data.

A marked-up version showing amendments to claims 1 and 9 has been provided as a separate sheet from this amendment and is enclosed herewith.

REMARKS

Claims 1-16 are still on file.

Priority

Claims 1-16 claim priority on Canadian application N° 2,201,819 filed April 4, 1997.

Claim Rejections – 35 USC § 101

Claims 1 and 9 have been amended in order to not be directed to non-statutory subject matter. Claims 1 and 9, as amended, no longer claim a human being's pulmonary system. The preamble of claim 1 has been amended to claim an injection system that delivers a gaseous substance from a container to a patient through a conduit that is mountable to the patient's pulmonary respiratory system. Claim 9 has been amended to claim an injection system delivering a gaseous substance from a container to a patient or conduit mountable to the patient's pulmonary respiratory system, along with a ventilator that is also mountable to the patient's pulmonary respiratory system. Claims 2-8 are dependent on claim 1, and claims 10-16 are dependent on claim 9, and as such, all dependent claims contain the new limitations of their independent base claims. It is believed that rejections under 35 USC § 101 have been overcome.

Claim Rejections – 35 USC § 112

Claims 1 and 9 have been amended in order to recite an injection system for delivering a gaseous substance from a container to a patient. Claims 1 and 9 no longer recite the patient's respiratory system, they recite that the conduit and the ventilator are mountable to a patient's pulmonary system. Again, their dependent claims contain these limitations. It is believed that rejections under 35 USC § 112 have been overcome.

Claim Rejections – 35 USC § 102

Claims 1-3 and 9-11 are rejected by the Examiner under 35 USC § 102 as being anticipated by **Bathe et al.** The applicant asserts that nothing in **Bathe et al.** indicates that the concentration of gaseous substance injected varies from injection

to injection. Therefore, the invention claimed in the **Bathe et al.** document does not provide an apparatus that can vary the concentration of the gaseous substance from injection to injection. Claims 1 and 9 have been amended in order to point out these structural differences between the claimed apparatus and the prior art apparatus. Hence, the control unit has been claimed to be so configured as to control the valve assembly so that the variable opening of the valve is responsive to the inspiratory gas flow in the conduit so as to achieve a predetermined concentration of gaseous substance with respect to the inspiratory gas and furthermore, the control unit is so configured as to vary the predetermined concentration of the gaseous substance within a plurality of inspiratory phases of the patient based on the inspiratory gas flow data.

Nowhere does the prior art disclose or anticipate such a control unit. Therefore, the claimed invention is patentably distinguishable from the prior art. The prior art structure is incapable of performing this intended use, and that is to vary the concentration of the predetermined gaseous substance from injection to injection based on the inspiratory gas flow data that the control unit boxes receives and analyzes.

Claim Rejections – 35 USC § 103

As argued in applicant's response of March 15, 2002, since **Bathe et al.** does not provide an apparatus for the variation of concentration from one injection to another as explained above, it is therefore respectfully submitted that since the primary reference lacks at least an element of the claimed invention, its combination with the secondary reference (**Dietz**), remains devoid of this element and cannot render the dependent claims obvious.

No new subject matter has been added to the claims. The amendments to the claims are fully supported by the specification as originally filed, namely page 13, lines 13-17, page 18, lines 23-25, page 20, lines 4-12, page 22, lines 14-19, and page 22, line 26 to page 23, line 2, for example.

It is therefore respectfully submitted that the present application is in condition for allowance and a notification to this effect is earnestly solicited.

Respectfully submitted,

Dated: November 22, 2002 By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please note that [brackets] refer to deletions and underlines refer to additions.

IN THE CLAIMS:

The claims have been amended as follows:

1. (TWICE AMENDED). An injection system for [the delivery of] delivering a gaseous substance from a container to a patient [pulmonary respiratory system] through a conduit [coupled] mountable to the patient's pulmonary respiratory system; said injection system comprising:

a control unit controlling said injection system;

a valve assembly in connection with the conduit to selectively allow delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said control unit to be controlled thereby; and

a flowmeter quantitatively measuring inspiratory gas flow in the conduit; said flowmeter being coupled to said control unit to supply inspiratory gas flow data thereto;

wherein a) said control unit [controls] is so configured as to receive and analyze said inspiratory gas flow data and as to control said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow in the conduit so as to achieve a predetermined concentration of the gaseous substance with respect to the inspiratory gas, and b) said control unit is so configured as to vary said predetermined concentration [varies] within a plurality of inspiratory phases of the patient[.] on the basis of said inspiratory gas flow data.

Kindly amend claim 9 as follows:

9. (TWICE AMENDED). An injection system for [the delivery of] delivering a gaseous substance from a container to a patient [pulmonary respiratory system] through a conduit [coupled] mountable to the patient's pulmonary respiratory system[;] along with a ventilator also mountable to the patient's [the] pulmonary respiratory system [of the patient being also coupled to a ventilator] for forcing inspiratory gas therein; said injection system comprising:

a control unit controlling said injection system; said control unit being so configured as to receive and analyze [receiving] inspiratory gas flow data from the ventilator; and

a valve assembly in connection with the conduit to selectively allow delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said control unit to be controlled thereby;

wherein a) said control unit [controls] is so configured as to control said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow supplied to the patient so as to achieve a predetermined concentration of the gaseous substance with respect to the inspiratory gas, and b) said control unit is so configured as to vary said predetermined concentration [varies] within a plurality of inspiratory phases of the patient[.] on the basis of said inspiratory gas flow data.